



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/427,447 10/27/99 SZYNALSKI

A

EXAMINER

QM32/0302

RIMELL, S

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MORRISTOWN NJ 07960

ART UNIT

PAPER NUMBER

3712

#2 2

DATE MAILED:

03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/427,447

Applicant(s)

SZYNALSKI, ALEXANDER
GOEN

Examiner

Sam Rimell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
 2. ☐ received in Application No. (Series Code / Serial Number) ____.
 3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 11 set forth a method in which lobelia is used “in an amount effective to aid in the reduction or cessation of said tobacco smoker’s craving to smoke tobacco.” However, the disclosure does not reveal what this amount actually is. In fact, the disclosure does not reveal the therapeutically effective dosage amounts for any of the substances disclosed, so the specification is non-enabling for all of claims 1-20. Simply making reference to an OTC product, such as “Cigsation” or “Trim Specifics” is insufficient to meet the disclosure requirement since OTC products do not always label the dosages or contents of the of the substances they contain.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 1-20 are a claimed method in which he craving to smoke is alleged to be reduced or ceased by the use of education materials, hypnosis, and the ingestion of naturally occurring

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substances, such as lobelia. Additional substances, such as wood betony, licorice root, and peppermint are also alleged as being therapeutically effective. However, there is no evidence that the combined use of educational materials, hypnosis, and the recited natural substances produces a therapeutically effective method for reducing or eliminating a craving for smoking.

There is no clinical evidence that the combined effects will produce the claimed result. In addition, the reference to Schneider et al. (US Pat. 5,414,005) contains a statement in column 3, lines 5-9 that orally ingested lobeline has never been shown to be therapeutically effective in reducing a craving for smoking. Since the other required steps of providing educational materials and providing hypnosis have also never been shown to be therapeutically effective, there is no reason to assume that the combined usage of educational materials, hypnosis and lobeline will be therapeutically effective.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by admitted prior art to Vitamerica Inc .

Applicant's disclosure admits (page 5, para 4) that lobeline is utilized in a known prior art ingestible product known as "Cigsation". Applicant's disclosure (page 26, para 2) admits that all the remaining claimed substances are contained in a known prior art ingestible product called "Trim Specifics". Applicant's disclosure further admits (page 11, para 4) that the hypnosis and

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education steps are contained in a known prior art tape program called "Smoking Cessation". All of these products are available from a common source, known as Vitamerica Inc., and are available on the internet at www.vitamerica.com. Since each of these products derives from a common source, it is reasonable to presume that they are intended to be used together in a method for addressing a smoking addiction.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.



Sam Rimell
Primary Examiner
Art Unit 3712